

Sodium Chloride

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
Macron Fine Chemicals™	H672	Sodium Chloride, Multicompential	R
Macron Fine Chemicals™	H675	Sodium Chloride, IP	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The **USP and Multicompential** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The **IP** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth in the Drugs and Cosmetics Rules, 1945, Government of India Ministry of Health and Family Welfare.

A number of the cGMP produced products that are sold by Avantor Performance Materials, LLC. may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures in place at our facilities we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

Section 3 – Physical/Chemical Information

CAS #: 7647-14-5

Manufacturing Process: Synthesis, Batch Process

Raw Material Origin: Chemical

Section 4 – Regulatory Information

DMF: Avantor Performance Materials, LLC. does not carry a Drug Master File for these products.

BSE/TSE Status: The subject materials are manufactured from raw materials that contain NO animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products. Therefore, a product claimed synthetic on the Certificate of Origin may be considered as Negligible Risk for Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE) per the requirements in EMEA/410/01 rev. 3.

Allergen/Hypersensitivities Information: The products listed do not contain latex, gluten, aspartame, antibiotics, benzoates (including benzoic acid, sodium benzoate, crustacean crab, crayfish, lobster, prawn and shrimp, egg, ethanol, fish and fish products, galactose, hydroxybenzoic esters, lactose, milk and milk products, Peanut (Arachis Hypogea), Walnut (Juglans nigra), Almond oil, Macadamia nut oil, Prunus dulis, Phenylalanine, Pollen propolis or royal jelly, Potassium and Sodium salts, Saccharin, Sesame seed products, Soy and soy products, sorbates, sucralose, sugars(fructose, glucose, honey, invert sugar, lactose, maltose, and sucrose), sulfites, and tartrazine. These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

GMO Information: The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

Aflatoxins: Aflatoxins as defined by IPEC (International Pharmaceutical Excipient Council) are a group of structurally related toxic compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed. The materials mentioned in Section no.1 are not from any substances of Aflatoxin sources and neither coming from Aflatoxin sources.

Residual Solvents/Organic Volatile Impurities (OVI) Information: To the best of our knowledge, the subjected materials comply with the requirements of ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the Sodium Chloride (H672, H675) product.

Elemental Impurities: Please see attached summary for Elemental Impurity information for these products.

Halal Status: The subject materials mentioned in section no.1 is Halal certified. Please refer to the customer support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: Halal)

Kosher Status: The subject materials are not Kosher Certified. Please refer to the customer support section of our website for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher)

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the C of A are reported as YYYY/MM/DD from our ERP system effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01.

Shelf Life Information: If a product has an assigned expiration or retest period, the date will appear on the certificate of analysis. For products that do not have assigned dates please contact Technical Support through the customer support section of our website for our product stability profiles. Ask Avantor Keyword: Expiration)

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. Ask Avantor Keyword: MOC)

Batch Definition: A batch is a homogenous unit of production.

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance if you require further documentation (Trade.Compliance@Avantorsciences.com).

Storage Requirement: Handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

Rev. 0; Effective Date: December 27, 2012 (MCH)

Rev. 1; November 21, 2019: Entire document on new letterhead, updated Section no. 2 MOC codes, updated Section no. 4 for Aflatoxin statement, TSE and BSE statement, Residual solvent statement, added Elemental impurity declaration and removed Residual Metallic catalyst; Section no. 5: Added COA Date Format statement, Shelf life information, Batch definition, Storage requirement, Kosher Statement and Country of Origin statement.(MK)

This electronic document is valid without a signature.

Section 7 – Contact Information

Technical Service Department
Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
Technical.Service@avantorsciences.com

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The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle.

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Material Name: Sodium Chloride

Product Code: H672, H675

Source/Type of Excipient: ☐ Mineral; ☐ Mineral Derived; ☐ Plant; ☐ Plant Derived; ☒ Synthetic; ☐ Fermentation Derived;
Other (explain):

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Arsenic	As	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm	ICP (0.2 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	5 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 1 ppm	ICP (1 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Max 1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 1 ppm	ICP (1 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 1 ppm	ICP (1 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 1 ppm	ICP (1 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 2 ppm	ICP (2 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 1 ppm	ICP (1 ppm)	Avg. of 3 batches

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/ unit (or range)		Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 5 ppm		ICP (5 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 5 ppm		ICP (5 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm		ICP (0.5 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 5 ppm		ICP (5 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm		ICP (0.5 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	2 ppm		ICP (0.5 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	5 ppm		ICP (1 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 2 ppm		ICP (2 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Less than 2 ppm		ICP (2 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm		ICP (0.5 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental impurities, step 4 version, 2014

Authorized Signatory



Avantor Performance Materials India Limited.